

Beacon NMNC 7.300.01 Zulresso (Brexanolone)

MEDICAL NECESSITY CRITERIA

Authorization Criteria

Member must meet ALL of the following criteria for authorization:

1. Member is 18 years of age or older
- AND
2. Member is 6 months post-partum or less
- AND
3. Has a major depressive episode no earlier than the third trimester and no later than 4 weeks after delivery
- AND
4. Diagnosis of post-partum depression (PPD), defined as above (#3), is confirmed by a psychiatrist
- AND
5. Documentation of a standard rating scale that reliably measures depressive symptoms, indicating moderate to severe major depression (e.g., Hamilton Depression Rating Scale [HAM-D], Montgomery-Asberg Depression Rating Scale [MADRS], Beck, PHQ-9)
- AND
6. Prescriber and/or the prescriber's healthcare setting is certified in the Zulresso REMS program

The authorization will be issued one time per year.

CONTINUED STAY CRITERIA

N/A

DISCHARGE CRITERIA

N/A

REFERENCES

1. Kaner S, Colquhoun H, Gunduz-Bruce H, et al. Brexanolone (SAGE-547 injection) in post-partum depression: a randomized controlled trial. *Lancet* 2017;390:480-489.
2. Meltzer-Brody S, Colquhoun H, Riesenbergr R, et al. Brexanolone injection in post-partum depression: two multicenter, double-blind, randomized, placebo-controlled, phase 3 trials. *Lancet* 2018;392: 1058-1070.